

Appl. No. 09/655,232  
Amdt. dated November 14, 2005  
Reply to Office Action of October 3, 2005

### **REMARKS**

Applicant has received and carefully reviewed the Office Action dated October 3, 2005, in which claims 6-9, 13-21 and 24-42 are pending, claims 6-9, 13-21 and 24-26 have been rejected and claims 27-42 are withdrawn from consideration. Favorable reconsideration is respectfully requested in light of the following comments.

#### ***Claim Amendments***

Claim 6 has been amended to recite "an expandable member having an expandable portion" and "opaque markers positioned on the expandable portion of the expandable member." This clarifying amendment adds no new matter. Support can be found, for instance, in Figure 5.

#### ***Claim Rejections—35 U.S.C. § 103***

Claims 6-9, 13-21 and 24-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ishida et al. (U.S. Patent No. 5,002,556) in view of Tanabe et al. (U.S. Patent No. 4,838,879) and Becker et al. (U.S. Patent No. 5,021,043). Applicant respectfully disagrees and submits that a prima facie case of obviousness has not been made.

Ishida et al. are directed toward a catheter assembly including a removable occlusion balloon. As the Examiner noted, "The material of the balloon 5 may be mixed with X-ray opaque substance such as platinum, gold or the like which constitutes a marker." Column 4, lines 19-21. Ishida et al. additionally teach, "[t]he distal portion 24c of the balloon 24 may be made solid, and a belt-type marker 24d made of X-ray opaque substance as described above may be fixed to or embedded in the outer peripheral surface of the portion 24c." Column 6, lines 54-58. Notably, this distal portion is solid and is consequently not expandable. There is thus no

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indication in Ishida et al. of opaque markers positioned on the expandable portion of the balloon. Further, even though Ishida et al. teach that the balloon can be mixed with X-ray opaque substance to turn the balloon into a marker, Ishida et al. do not teach that expandable markers can be positioned on the expandable portion of a balloon.

Two arguments are put forth in the Office Action to make the case for obviousness, first that mere duplication of a well known element in an apparatus does not constitute patentable subject matter, and second that Tanabe et al. teach the use of opaque markers in a catheter arranged in a particular pattern.

With regard to the duplication of elements, the opaque markers do not constitute a duplication of unrelated elements; the opaque markers as a whole are the element. Just as the tick marks on a measuring tape provide a way to measure the length of objects, the opaque markers on the expandable portion of the balloon provide a way to measure the length of intravascular features. As such, the opaque markers are not merely duplicative but provide additional functionality that a single opaque marker lacks. An obviousness rejection based on Ishida et al. in view of this case law thus fails on these grounds.

With regard to the second argument, Tanabe et al. are directed toward a catheter having a curved distal end portion having at least one radio opaque ring member for indicating the direction of the end portion. The catheter is not expandable nor is there any indication that the radio opaque ring members are expandable. Indeed, "radio opaque ring member 3 is preferably made of stainless steel, gold, a titanium nickel alloy or the like." Column 4, lines 43-45. These are materials known to not be expandable. There is no suggestion that the radio opaque rings of Tanabe et al. are suitable for use on expandable portions of expandable members. If one or more radiopaque rings as described in Tanabe et al. were placed on the expandable portion of the

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balloon of Ishida et al., it would render the balloon unfit for its primary purpose as an *expandable* occlusive device. There is no suggestion or motivation to modify Ishida et al. in view of Tanabe et al. to produce a device as claimed in claim 1.

Becker et al. is directed towards a lacrimal dilation catheter. The catheter may include one or more visually perceptible markers having a known spaced relationship to one of the ends of the inflatable member. The markers are "established by permanent indelible ink which is placed directly on the exterior of the shaft of the catheter 36." Column 6, lines 45-47.

There is no suggestion to modify either Ishida et al. or Tanabe et al. in view of this reference to replace the radiopaque markers with ink markers. Markers made of indelible ink may not be radiopaque and thus would be useless in a procedure requiring X-ray visualization like the procedures describing the use of the devices of Ishida et al. and Tanabe et al. Unlike the lacrimal procedures described in Becker et al. where positioning is apparently possible through the use of visually perceivable markers, the intravascular procedures of Ishida et al. and Tanabe et al. happen deep in tortuous blood vessel systems of a body, and positioning is generally possible only with fluoroscopy or other technique of seeing through the body tissues. Indelible ink or other visually perceivable marker is of no use with such techniques. Substituting the radio opaque marker of Ishida et al. with the ink marker of Becker et al. would render the device of Ishida et al. unsuitable for use with a procedure requiring fluoroscopy and thus unsatisfactory for its intended purpose. There is thus no motivation or suggestion for modifying Ishida et al. in view of Becker et al.

In sum, Ishida et al. do not disclose opaque markers on an expandable portion of an expandable balloon nor do Ishida et al. disclose opaque markers suitable for use on the expandable portion of an expandable balloon. Tanabe et al. do not disclose opaque markers

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suitable for use on the expandable portion of an expandable balloon, and there is thus no suggestion or motivation to modify Ishida et al. in view of Tanabe et al. Becker et al. disclose only markers established by permanent ink and thus do not provide markers for which there is any motivation to modify Ishida et al.

As there is no motivation or suggestion to combine any of the references, Applicant respectfully submits claim 6 is non-obvious over the cited references and is in condition for allowance. As claims 7-9, 13-21 and 24-26 depend from claim 6 either directly or indirectly and contain additional claim elements, Applicant submits that these claims are also in condition for allowance.

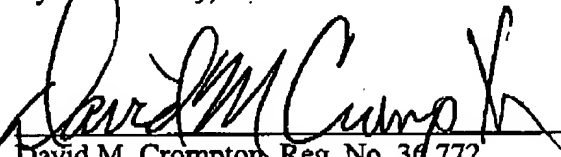
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Stewart M. Kume

By his Attorney,

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